

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE: FRESENIUS
GRANUFLO/NATURALYTE
DIALYSATE PRODUCTS LIABILITY
LITIGATION**

**MDL NO.: 1:13-MD-2428-DPW
FILED UNDER SEAL
LEAVE TO FILE GRANTED ON 10/12/17**

This Document Relates to:

Mervin Boyd, et al. No.1:13-cv-11717

Charles Cameron, et al. No.1:13-cv-12446

Daniel Carter, et al. No. 1:13-cv-12459

Joyce Marie Clark, et al. No. 1:13-cv-12460

Kathy Dennis, et al. No. 1:13-cv-12467

Gloria Cothorn Dunaway, et al. No. 1:13-cv-11714

Janice McGhee, et al. No. 1:13-cv-13172

Michael McNulty, et al. No. 1:13-cv-12403

Kimberly Ross, et al. No. 1:13-cv-12478

Sophia Walker, et al. No. 1:13-cv-12487

Beulah Williams, No. 1:13-cv-12486

REDACTED
RESPONSE IN OPPOSITION TO MOTION FOR SUMMARY JUDGMENT ON THE
CLAIMS OF OPT-OUT PLAINTIFFS THAT ARE BARRED BY THE LEARNED
INTERMEDIARY DOCTRINE

NOW INTO COURT, through undersigned counsel, come the above-referenced Plaintiffs, who file their Response in Opposition to Motion for Summary Judgment on the Claims of Opt-Out Plaintiffs That Are Barred By The Learned Intermediary Doctrine, and opposing the Motion for Summary Judgment, would show unto the Court the following:

The Fresenius Defendants are asking this Court to act as both Judge and Jury, and the Court should decline to do so. There are genuine issues of material fact regarding whether the Learned Intermediary Doctrine bars these claims, and questions of fact are properly the province of a jury. The motion for summary judgment should be denied.

STANDARD FOR SUMMARY JUDGMENT

The standard for summary judgment is well-known. Summary judgment is appropriate only if there are no genuine issues of material fact and movant is entitled to judgment as a matter of law. Fed. R. Civ. Pro. 56. *Cross v. Cummins Engine Co.*, 993 F.2d 112 (5th Cir. 1993). Disputes over facts that might legitimately affect the outcome are material and, in applying the test, the court must view the evidence in the light most favorable to the nonmovant. *Anderson v. Liberty Lobby*, 477 U.S. 242 (1986).

SUMMARY OF THE ARGUMENT

As Judge Kirpalani correctly noted in his Omnibus Memorandum of Decision and Order on Major Motions In Limine in the *Ogburn* bellweather case, attached hereto as

Exhibit 1¹ the matter of whether the learned intermediary doctrine bars these claims, “is replete with factual issues, such as whether warnings and instructions were communicated, to whom they were communicated and whether those persons, if any, qualify as learned intermediaries.” It is properly the role of a finder of fact to decide if, based on the evidence presented, Defendants can prove the elements of a learned intermediary defense. Because questions of fact are properly the province of a jury, the motion for summary judgment should be denied.

A. Under the Learned Intermediary Doctrine, the issue of a warning’s adequacy is factual and should be determined by a jury.

Mississippi adheres to the “learned intermediary” doctrine, which holds that where prescription drugs are concerned, a manufacturer’s duty to warn extends to physicians and not to laymen. *Windham v. Wyeth Laboratories, Inc.* 786 F.Supp. 607, 611 (S.D. Miss. 1992). “The drug manufacturer has a duty to adequately warn the prescribing physician of any known adverse effects which might result from use of its prescription drug.” *Wyeth Laboratories, Inc. v. Fortenberry*, 530 So.2d 688 (Miss. 1988). *Wyeth* holds the adequacy of a warning is factual and should be determined by a jury. *Id.* at 692. The issue of a warning’s adequacy is factual and usually will be resolved by the trier of fact. *Id.* at 692. “To be reasonable, the warning should neither understate nor overstate the known risks associated with the use of a particular product.” *Thomas v. Hoffman-LaRoche, Inc.*, 949

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Ex.1, *Alysia Ogburn-Sisneros v. Fresenius Medical Care Holdings, Inc. & Others*, Commonwealth of Massachusetts, Superior Court Department of the Trial Court, Civil Action No. 05050.

F.2d 806, 811 (5th Cir. 1992) (citing *Wyeth*, 530 So.2d at 691-692).

Under the provisions of Miss. Code Ann. §11-1-63(c)(ii), the Mississippi Product Liability Act, in the case of a prescription drug, “an adequate product warning...is one that a reasonably prudent person in the same or similar circumstances would have provided...taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product.” *Wyeth*, 530 So.2d at 691.

B. The Fresenuis Memoranda were not intended to be “Warnings.”

The Fresenius memos listed in Defendants' Motion were never intended to be product warnings, and as such, the Fresenius memos were not used to adequately warn prescribing physicians of any known adverse effects which might result from the use of Granuflo or Naturalyte.

The Defendant has claimed that several Fresenius memoranda, issued between 2000 and 2011, adequately warned a prescribing physician of known adverse effects which might result from the use of GranuFlo or NaturaLyte. The memoranda are Ex.

(██████████████████████). However, Fresenius has, by the testimony of Jeffrey Gibbs, Esq., its regulatory expert, admitted that the memos were not product related and were not actual warnings.

■ [REDACTED]
 ■ [REDACTED]

[REDACTED]

Similarly, in answers to interrogatories propounded by the United States Department of Justice, Fresenius object[ed] to Interrogatory [No. 5(d)] [REDACTED]

[REDACTED]

[REDACTED] Also, Fresenius stated that the FMS Chief Medical Office considered a December 7, 2000 internal memo [REDACTED]

[REDACTED]²

Defendant's inconsistent position (that Fresenius Memoranda were not product warnings) was also enumerated in correspondence with the FDA. As discussed in

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Ex. "4", *Id.* at 0475.0020.

attachments to a March 14, 2013 letter from Brian Burns, FMCNA Senior Vice President of Quality Systems and Regulatory Affairs, to Muiatahar Shamsi of the FDA, Fresenius' position was [REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]³

C. There is no evidence that Plaintiffs' treating physicians acted as informed intermediaries.

The safety of GranuFlo and NaturaLyte as a dialysate component depends on its proper use, which in turn requires adequate warnings. There is overwhelming evidence that both NaturaLyte and GranuFlo were distributed and sold for use in an environment of widespread confusion - about which Fresenius knew, and which Fresenius caused - concerning the proper and safe use of NaturaLyte and GranuFlo as they relate to total buffer delivered to dialysis patients, including the Plaintiffs' Decedents herein. This confusion was evident and has been documented repeatedly. The following are just a few examples: [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

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Ex. "5," GF-PL 0066 at 0066.011 (FMC-MDL - 0021341 [REDACTED])

[REDACTED]

[REDACTED]

In its Answer to Interrogatories Propounded by United States Department of Justice, (In re - Fresenius Medical Care Holdings, Inc., Civil Investigative Demand No. 12-404 (W . D . L a .) , F r e s e n i u s s t a t e d :

“ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].”⁴

As the Summary Judgment record reflects, there is nothing to support the contention that Plaintiffs’ nephrologists or treating physicians specifically chose to use GranuFlo or NaturaLyte as a result of an “evaluat[ion of] the potential risks and benefits of [taking the product].” *Garside v. Osco Drug, Inc.* 976 F.2d 77, 80 (1st Cir. 1992) (citing *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806 (5th Cir. 1992)).

There is no evidence and therefore can be no assertion that the use of Defendant’s acid concentrate products was the result of a treating physicians’ professional medical opinion/decision regarding use of GranuFlo and NaturaLyte. Defendant’s Statement of Undisputed Material Facts in Support of FMCNA’s Motion for Summary Judgment contain assertions that treating nephrologists/physicians “received access to FMCNA’s Doctor’s Corner Intranet site” (paragraphs 65,66, 79) or “would have been sent any Chief Medical

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Ex. “6,” GF-PL-0475 at 0475.0009 (FNCONDK 1000039541) Fresenius Medical Care Holdings, Inc. Response to Interrogatories.

Office Memoranda....that relate to issues such as GranuFlo and NaturaLyte serum bicarbonate levels and acetate conversion” (paragraphs 67,80, 123, 124). However, there is no evidence in this record that the treating doctors knew at the relevant time all the information which would have been included in a proper warning. There is no evidence that the treating physicians actually reviewed the documents that were purportedly available on Doctor’s Corner or, if they did, what conclusions they reached as a result of any information contained there, and what actions they undertook with regard to treatment of these Decedents. There is no evidence whatsoever regarding the specific treating physicians identified in FMCNA’s Statement of Facts and their decision to prescribe either GranuFlo or NaturaLyte.

Discovery thus far has been limited to issues of general causation or of specific causation as to Decedents in the bellweather trials. No case-specific discovery has been undertaken as to the Decedents to which this motion applies, and the Court acknowledged during the most recent status conference that these motions go to the issue of causation generally. Whether the Defendant can prove the elements of the Learned Intermediary defense are necessarily case-driven issues of fact and therefore inappropriate for summary judgment.

E. In the Alternative, Plaintiffs Request Additional Time Pursuant to Rule 56(d)

In the alternative, Plaintiffs request additional time pursuant to Rule 56 (d) to respond to the Motion for Summary Judgment Based on the Learned Intermediary Doctrine. The affidavit of Dunbar Watt is attached hereto as Exhibit 9.

CONCLUSION

The Fresenius Defendants had a duty to adequately warn prescribing physicians of any known adverse effects which might result from use of its prescription drugs GranuFlo and NaturaLyte. The Defendants can not identify any “warnings” given to treating physicians. There is no evidence whatever in the record that Plaintiffs’ treating physicians acted as informed intermediaries in this case. There is, however, evidence of widespread confusion regarding the safe use of GranuFlo and NaturaLyte among Fresenius employees, including Medical Directors at Fresenius clinics where Plaintiffs’ Decedents were dialyzed. All of the aforementioned are genuine issues of material fact which preclude summary judgment in this case.

This the 16th day of October, 2017.

Respectfully submitted,

BY: DOWDY COCKERHAM & WATT

s/Dunbar Watt
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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court using the ECF system which sent notification of such filing to all attorneys of record.

THIS the 16th day of October, 2017.

/s/Dunbar Watt
Dunbar Watt